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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2711-2730

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs*.

WASHINGTON, D. C., January 3, 1950.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2711. Misbranding of Foille Emulsion. U. S. v. 77 Bottles, etc. (F. D. C. No. 26960. Sample Nos. 53355-K to 53358-K, incl.)

LABEL FILED: March 28, 1949, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about February 9 and July 15, 1948, and January 21 and March 15, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 2 1-pint bottles, 1 1-gallon bottle, and 60 1½-ounce bottles of *Foille Emulsion* at New Orleans, La., together with 14 sample kits, each containing one bottle of *Foille Emulsion*, one tube of *Foille Ointment*, and various pieces of literature.

*For new drug shipped without effective application, see No. 2713; cosmetics, subject to the drug provisions of the Act, Nos. 2726, 2727.

LABEL, IN PART: (Bottle) "Foille Emulsion A Protective Dressing. Analgesic-Antiseptic. Ingredients: Benzocaine, Carbolic Acid (Less than 2 Percent), Calcium Oleate, Calcium and Potassium Iodides, Oxyquinoline Base, Calcium Thiosulfate and sulphur in a Vegetable Oil Base * * * Directions: Apply liberally to gauze compress or directly to wound area."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form as are necessary for the protection of users. The article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply liberally to gauze compress or directly to wound area" and (brochure entitled "Burns") "Dressing saturated with Foille Emulsion should be applied directly to the wound and the dressing kept moist with Foille. * * * In some cases, * * * it may be appropriate to continue with the original dressings for a longer period of time by frequently saturating them with Foille in order to keep the area moist, soft, and pliable. Such treatment may be continued either with or without changing the dressings until healing is complete or until conditions are satisfactory for grafting. * * * Foille Emulsion is applied directly to the injured areas either by pouring, spreading with a camel's-hair brush or spraying with a special atomizer. Under open, cradle treatment method, Foille Emulsion is reapplied at regular intervals, either with saturated compresses or direct without benefit of dressings as indicated above."

DISPOSITION: April 28, 1949. Default decree of condemnation and destruction.

2712. Misbranding of Foille Emulsion. U. S. v. 9 Bottles, etc. (F. D. C. No. 26953. Sample Nos. 53430-K, 53431-K.)

LABEL FILED: March 24, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about January 17, February 22, and March 14, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 9 16-ounce bottles, 15 4-ounce bottles, 279 1½-ounce bottles, 2 1-gallon bottles, and 6 1-quart bottles of *Foille Emulsion* at Birmingham, Ala., together with 2 brochures entitled "Burns" which were delivered by a representative of the shipper.

LABEL, IN PART: (Bottle) "Foille Emulsion A Protective Dressing. Analgesic-Antiseptic. Ingredients: Benzocaine, Carbolic Acid (Less than 2 Percent), Calcium Oleate, Calcium Thiosulfate and sulphur in a Vegetable Oil Base * * * Directions: Apply liberally to gauze compress or directly to wound area."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply